Substitute Specification -- Marked-Up Portions

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[0059] **BRIEF DESCRIPTION OF THE DRAWINGS**

[0060] The present invention will be more fully understood from the following detailed description of the preferred embodiments thereof, taken together with the drawings, in which:

[0061] FIG. 1A is a simplified pictorial illustration of an apparatus for modifying and removal material and biological tissue, in accordance with a preferred embodiment of the present invention.

[0062] FIG. 1B is a simplified pictorial illustration of an exemplary pattern for depositing High Absorption Substance (HAS) on the intermediate material of the apparatus for modifying material and removal of biological tissue, in accordance with a preferred embodiment of the present invention.

[0063] FIG. 1C illustrates the pattern and direction of heat diffusion following the energy deposition in the pattern of HAS of FIG. 1B.

[0064] FIG. 1D illustrates an exemplary pattern for High absorbing substance placed on the intermediate material.

[0065] FIG. 1E illustrates the extent of thermal diffusion of the energy in the target material in response to the energy deposition in the high absorbing substance pattern in the intermediate material as shown in FIG. 1B.

[0066] FIG. 1F illustrates an exemplary pattern for High absorbing substance placed on the intermediate material and the corresponding thermal energy deposition in the target material.

[0067] FIG. 2A is a simplified pictorial illustration showing an apparatus for modifying a target material, in accordance with a preferred embodiment of the present invention.

[0068] FIG. 2B is a simplified pictorial illustration showing an apparatus for modifying a target material, allowing the intermediate material to be lifted to allow energy removal directly from the target material.

[0069] FIG. 3A is a simplified pictorial illustration showing an apparatus for modifying a target material.

[0070] FIG. 3B is a simplified pictorial illustration of possible patterns and shapes of the high energy absorbing substance.

[0071] FIG. 3C is a simplified pictorial illustration showing additional possible patterns and shapes of the high energy absorbing substance.

[0072] FIG. 4 is a simplified pictorial illustration showing an exemplary device for material removal and modification and the device related controls.

[0073] FIG. 5 is a simplified pictorial illustration showing in greater details an exemplary control box for the device for material removal and modification.

[0074] FIG. 6 is a simplified pictorial illustration showing in greater details an exemplary device for material removal and modification.

[0075] FIG. 7A is a simplified pictorial illustration showing an exemplary method for material removal and modification using a stationary beam method.

[0076] FIG. 7B is a simplified pictorial illustration showing an exemplary method for material removal and modification using a moving beam method.

[0077] FIG. 7C is a simplified pictorial illustration showing an exemplary method for material removal and modification using a broad beam method.

[0078] FIG. 7D is a simplified postorial illustration ~~photograph~~ showing an exemplary cap with an exemplary intermediate material used in a device for material removal and modification.

[0079] FIG. 7E is a simplified postorial illustration ~~photograph~~ showing an exemplary cap with an exemplary intermediate material mounted on a box containing the energy source and energy removal element used in a device for material removal and modification.

[0080] FIG. 7F is a simplified pictorial illustration showing a time-sequence of energy deposition, energy removal and additional energy deposition as practiced by a preferred embodiment of the present invention.

[0081] FIG. 8 is a simplified pictorial illustration showing the method of peeling intermediate material used in the present invention for target material removal and modification.

[0082] FIG. 9 illustrates a telescopic attachment for adjusting the distance of the high absorbing substance film from the energy focusing element.

[0083] FIG. 10 illustrates four parameter regimes that interact together to bring about the desired target modification effect.

[0084] FIG. 11 illustrates the effect of the density of particles of high absorbing substance on the amount of energy coupled to the target surface.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

[0085] ~~[0082]~~ The use of a highly controlled heating and cooling is contemplated. For example, one of the preferred embodiments is illustrated in FIG. 1A: A thin, highly conducing intermediate material (HCM, for example a thin sheet of Aluminum) 120 [[20]] is attached to a target material 10 such as the skin [[10]]. The HCM 120 is coated at specific points with high absorbing substance [[30]] (HAS) 130. A source of energy 140 delivers a dose of energy to the intermediate material 120. The intermediate material 120 absorbs this energy and conducts it to the target material 10. In the particular embodiment of FIG. 1A, the source of energy 140 is a [[The]] laser beam [[is]] directed towards one such location of high absorbing substance (HAS) 130 -coated material. The heat is absorbed by the HAS 130 and conducted through the layer of highly conducting material 120. For example we calculate that in a circular area of 1 cm^2 heat will [[be]] diffuse to a depth of about 600 um in about 0.36 sec or 360 ms, in water-like substance. The energy source 140 [[40]] is on for the duration of time corresponding to power of the energy source allowing sufficient energy to be deposited. Immediately following the interaction a coolant ejector 150 discharges a coolant spray 160 from a coolant reservoir 170 ~~60 from a coolant ejector 50 is discharged~~ allowing immediate cooling of the target area through the ~~HCM~~ film of HCM 120. One can design the film thickness and size so that the resultant energy per unit time is sufficient to achieve the desired effect.

[0086] ~~[0083]~~ In 360 ms the thermal diffusion in a water-like tissue target material is on the order of 600 um. On the other hand a circular area of 3 mm^2 will be evenly heated up by a scanned energy source contemplated in one preferred embodiments of this invention, in about 36 ms by an exemplary scanning of the optical light. During this time, heat diffuses only a ≈200 um. This will be more in line with the thermal tissue damage that we wish to take place. Such a small volume, small size intermediate material will allow the use of a single stationary beam. One can then use a MECHANICAL device 165 (for example a drum-like switcher, [[(]] much like in a revolver pistol) that will move small, mirrored faces 167 [[47]] to move the beam 168 [[48]] around to the various spots of high absorbing substance 130 [[30]].

[0087] ~~[0084]~~ Alternatively the intermediate material 120 [[20]] in FIG. 1A can be made of a THERMALLY NON-CONDUCTING thin intermediate medium. The highly absorbing substance 130 [[30]] is deposited on the intermediate material 120 and the process continues as

described above. The main difference between the two methods is that very little lateral conduction occurs with the intermediate material 120 [[20]] made of Non-conducting material. On the other hand, efficient transfer of thermal energy from the spots of HAS 130 ~~spots 30~~ to the target material is ensured by using a very thin layer of intermediate material 120 [[20]]. This has the advantage that while no photons or high absorbing substance comes in direct contact with the target material, the heat is quickly and efficiently transferred to the target and can then be just as efficiently and quickly eliminated.

[0088] ~~[0085]~~ In either one of the above preferred embodiments, the intermediate substance can be made so there is no direct contact or interaction of the energy from the energy source (for example, photons from an electromagnetic energy source) NOR direct contact of the highly absorptive material HAS with the target material. For example, only the sterile outer surface of the intermediate material makes direct contact or has direct interaction with the target material.

[0089] ~~[0086]~~ In the embodiment that envisions a non-conducting intermediate material, the highly absorbing substance, HAS, can be precisely deposited at the selected locations on top of the intermediate material. Since thermal diffusion in the lateral direction is very limited the interaction is confined to substantially the area where the HAS is exposed to the energy beam. For example, if the non thermally-conducting intermediate material is a water-like material with water-like thermal properties, with approximately 100 um thickness, it will conduct thermal energy through in about 10 ms. The thermal interaction with the target material will start within less then 10 ms and the lateral heat diffusion, if, for example, we deploy the energy removal system within 40 ms, will be confined to boundary of 200 um from the energy deposition zone (i.e. the lateral distance from the zone where the HAS is deposited).

[0090] ~~[0087]~~ In fact, by controlling the lateral spatial separation between the HAS zones one can create a continuum of thermal deposition. ~~This is shown in FIG. 1F where the pattern 82 of highly absorbing substance 30 deposited on the intermediate medium 20, becomes after thermal energy diffusion, a substantially uniform target material modification pattern, 85, on the target material 10.~~

[0091] ~~[0088]~~ Similarly the process can contain sources other then light (for example a broad band light source, a xenon or halogen lamp) in synchronized use with the coolant.

[0092] ~~[0089]~~ In one such preferred embodiment, a thermo-electric cooler (TEC) can be employed. Here the TEC is off during the energy deposition phase. The TEC is then turned on to remove energy and quench the interaction at a precisely desired moment. Alternatively, in another preferred embodiment, the TEC can also act as an energy source and heat up the targets material, then the electric current polarity is reverse and the TEC can then acts as an energy removal element and rapidly cool the target material.

[0093] ~~[0090]~~ However, cryogen spray is more easily and rapidly controlled. In yet another preferred embodiment, the TEC polarity may be reversed rapidly and in a controlled manner upon the generation of a signal from the user or a controller unit. In this embodiment, the TEC acts as both the energy source and as an intermediate material. Heating of the target material takes place and modification of the target material follows. The TEC controller then causes heating of the target material to stop at a desired moment in time, and the removal of energy and/or cooling to follow in order to quench the interaction.

[0094] ~~[0091]~~ In yet another preferred embodiment a thermoelectric cooler can be combined with the process of coblation or electric-cautery or electric-surgery to achieve rapid energy removal following energy deposition in order to minimize pain and control damage and control target material modification. The same process can also be applied to the process of coblation where energy removal and minimization of pain can be achieved by application of energy removing to the target material after any and all plasma mediated interactions. In this embodiment, the energy removing can be achieved by using thermo-electric cooler, a peltier cooler, coolant spray, cryogen spray as well as a host of other energy removal mechanism. All of these will work provided that the user allow the modifying interaction to take place and then, at a predetermined point in time, the user activate one of the above energy removal methods. This applies to the processes of ablation that can be envisioned as well except that ablation takes place by electro-surgery or Coblation or plasma generation, or plasma-mediated material removal, or rapid generation of heat. Again, cooling occurs either THROUGH the highly conducting material (for example if aluminum is used), or if electrodes are used for delivering electric, electromagnetic, irradiative, or chemical energy. And it will also work if one raises the intermediate material to allow directed application of the energy removing substance (or coolant) to the target material ~~as shown in FIG. 2B where the intermediate material 340 is lifted up to allow the energy removal substance to be applied directly to the targeted tissue 10~~ following the

interaction. This also ensures minimization of pain with all methods including electro-cautery/hyfercator.

[0095] ~~[0092]~~ In yet another preferred embodiment, the intermediate medium consists of an electrical heater in contact with the target material. The electrical heater may be pulsed or may be on continuously. IF it is on continuously, a pulsed energy removal system is employed. For example, a sufficiently think intermediate material, said intermediate material is also a heater or capable of heating the target material, which is then sprayed by a cryogen spray or cooled by other coolant or energy removal means in order to modulate both intermediate material AND target material temperature and thermal energy content. The cryogen spray will also remove thermal energy from the target material through the intermediate medium. This will allow reduction of the target material temperature at the desired times.

[0096] ~~[0093]~~ With the above methods we can also aid in the removal of pigmented skin blemishes that can also be affected. This can be done much like the CO2 only much less expensive, pain-free, AND with a much better control of spatial targeting because of the high absorption substance deposition.

[0097] ~~[0094]~~ Another advantage of the embodiment envisioning the depositing of high absorbing substance (HAS) on a paper or thermally mediating medium but on the side-away from the skin is that the intermediate material or intermediate paper block any debris from the ablated target material. In addition, the high absorbing substance is not allowed to come in contact with the skin.

[0098] ~~[0095]~~ Attached below is an exemplary list of possible intermediate papers and or material that can serve as intermediate material:

[0099] ~~[0096]~~ A. The intermediate material can be prepared with the high absorbing substance embedded in it: Colored paper; Toilette paper; Tissue paper; and Paper matrix with the HAS embedded in its matrix.

[00100] ~~[0097]~~ B. Good conductors which may for example be shaped into a foil: Stainless steel; Steel; Aluminum; Copper; Gold; and Other metals.

[00101] ~~[0098]~~ The above method means contain both light and HAS within the Device. The target material or skin is never in direct contact with the material and is never exposed the to photons from an energy source.

[00102] ~~[0099]~~ C. An intermediate material for the delivery of energy may be devices such as hyfercator or electrocauterers with Cooling apparatus for energy removal

[00103] ~~[00100]~~ D. Coblation with Cooling

[00104] ~~[00101]~~ E. An alternative method may be a thermoelectric cooler with a laser acting as an energy source. The laser radiation may be activated in a pulsating mode while the energy removal (e.g. cooling) is synchronized with the heat source.

[00105] ~~[00102]~~ F. Energy may be pumped into the intermediate material using high resistance electrical wires. The intermediate material can then be cooled rapidly with a loop of thermally conducting tube containing a circulating cryogen or other water flow, or through the use of cryogen spray.

~~[00103] Another embodiment is shown in FIG. 2A--The Coolwand.™ There, the energy source (for example a laser source) 300 and the coolant source 310 are mounted inside the handpiece 320. The cap 330 is made of a conducting material or from a material thin enough to allow significant heat conduction from the inside part of the cap 330 to the outside part 335 in a short time--substantially shorter then about 0.5 second. The power supply 340 powers the instrument's energy source and cooling source.~~

~~[00104] The light from the energy source, (e.g. a laser or a broadband light source) is absorbed by a high absorbing substance (HAS) 350. The HAS 350 transfers its energy to the conducting part 355 which stretches throughout the intermediate material cap volume 370 is in contact with the target material 10. The rest of the intermediate material cap volume 370 is made of insulating material. Thus, by controlling the size and volume of the high conductive substance area=the high thermal conductivity area size 340, one determines how the size of the area to be affected. By controlling the power and the on time duration of the energy source, one determines how much energy will be delivered to what size area. By controlling the coolant, one determines the duration of time for which the interaction is allowed to go on. Thus, this embodiment allow for elimination of scanners, no moving parts, no contact of the HAS with the skin, and no~~

~~exposure of the skin to photons or any energy other then highly controlled thermal energy. There is also no microprocessors or programs to control this. It can all be made with hardwired design.~~

~~[00105] The high absorbing substance 350 is consumed within a given amount of time and thus allows a finite amount of time for use. The size of the high conductive material (HCM) 355 is adjustable to treat different areas shape and sizes. Each HCM 355 is packed within its own cap 330 making it a disposable cap. The Energy source power and duration are presets and corresponds to the size of the HCM size and design.~~

~~[00106] FIG. 1A illustrates one of the preferred embodiments: A source of energy 40; delivers a dose of energy to an intermediate material 20. The intermediate substance absorbs this energy and conducts it to the target material 10.~~

[00106] ~~[00107]~~ It is also possible that the intermediate substance 120 [[20]] may have on it a few absorbing locations 132 [[30]] where a substance of high absorbance HAS 130 with respect to the energy of the source 140 [[40]] has been applied. This energy is then absorbed by the high absorbing substance 130 locations 132 [[30]] which then transfer the energy ~~them~~ to the intermediate material 120 [[30]] which then transfer the energy to the target material 10. There, said energy modifies or ablate the target material 10. Subsequent to the interaction, (or, in some preferred embodiments during) a substance capable of energy removal 170 [[70]] is directed by the ejector/director 150 [[50]] to the intermediate material 120 [[20]] which is in contact with the target material 10. The substance capable of energy removal so directed [[60]] 160, then remove at least some of the energy from the intermediate material 120 [[20]] and thus also from the target material 10. This procedure allows, among other things minimization of pain in human tissue interaction and greater control of damage.

~~[00108] In further elaboration of this embodiment, the high absorption substance (HAS) 30 may be located at several different points thus allowing efficient delivery of energy to various locals on the intermediate material and target material. This too is illustrated in FIG. 1A.~~

[00107] ~~[00109]~~ In a further elaboration of this embodiment, the high absorption substance (HAS) 130 [[30]] may be located at several different points 132 [[30]] thus allowing efficient delivery of energy to various locals on the intermediate material 120 and target material 10. This will also spread out the energy deposition effect and will allow simultaneous deposition of energy in one location AND removal of energy in a second, adjacent location. Of course the

energy source [[40,]] 140 in this embodiment has to be stirred from one location 132 [[30]] to the next in a predetermined pattern. The stirring of the energy source can be accomplished by means of an energy-stirring device such as a mechanical device 145 [[45]]. The energy removal substance ejector/director 150 [[50]] can be synchronized with the beam stirring device 145 [[45]] to accomplished the above mentioned simultaneous energy deposition in one location and energy removal in a second location.

[00108] ~~[00110]~~ In a further embodiment the intermediate material 120 [[20]] may be made of a conductor or an insulator. If the intermediate material 120 is made up of a conductor--then depending on the thickness, of the plate, it may conduct well within a given interaction time (i.e. before the energy removing substance ERS is applied) to all regions of the plate [[20]] of intermediate material 120. However if the plate of intermediate material 120 is very thin, the flow of energy is limited by the cross section and is limited in the lateral direction. Energy flow will be efficient in the Z-direction (i.e. towards the target material). I.e., most of the energy shall be conducted directly, in the Z-direction towards the target material and very little energy shall be conducted laterally and then into the targeted material. The energy distribution in the intermediate material will be that shown by 172 [[65]] in FIG. 1B. Then, due to the finite thermal conduction in the intermediate material the final thermal energy distribution in the target material 10, will be that shown by 174 [[70]] in FIG. 1C where the concentric arrows indicate the direction diminishing thermal effect.

[00109] ~~[00110]~~ In another preferred embodiment, the intermediate material is made of a substantially thin thermal insulator. The energy from the energy source is then applied to the intermediate material via a high absorbing substance 130 [[30]] applied at any desired pattern as shown in FIG. 1D. Since the absorbed source energy is now converted to thermal energy but remains confined substantially to the shape of the HAS spots 132 [[30]] on the intermediate material [[20]] 120, at least some of this energy will be transferred to the target material 10 below, shown in FIG. 1E and diffuse further down towards the target material. If said target material is composed, for example, of tissue or water-like material, the thermal diffusion will be rather slow (for example it takes about 10 ms in such water-like material for thermal energy to diffuse a distance 100 um) and the thermal effect at the target by the time the energy removal system (or coolant) is activated, will be more confined, for example, to within the second ring 176 [[, 75,]] in FIG. 1E.

[00110] ~~[00112]~~ An additional preferred embodiment envisions the energy source as a rapid heater embedded within confining caps. These heaters may be made of electrical heaters. Alternatively, these heaters may be made of thermoelectric cooler with switchable polarity.

[00111] As discussed previously, by controlling the lateral spatial separation between the HAS zones one can create a continuum of thermal deposition. This is shown in FIG. 1F where the pattern 182 of highly absorbing substance 130 deposited on the intermediate medium 120 becomes, after thermal energy diffusion, a substantially uniform target-material modification pattern 185 on the target material 10.

[00112] ~~[00113]~~ An alternative embodiment is shown in FIG. 2A: The energy source (for example, a laser) 200 [[300]] and the energy removal source (for example a coolant) 210 [[310]] are mounted inside a handpiece [[320]] 220. The intermediate material 230 [[330]] is shaped like a cap 235 and is made of a conducting material 255 or from a material thin enough to allow sufficient amount of heat to be conducted from the inside surface of the cap 235 [[330]] to the outside surface of the cap 235 in contact with the target material 10 [[335]]. This conduction may be completed in a short time for example shorter then about 0.5 second. The power supply 240 [[340]] powers the instrument's energy source and cooling source.

[00113] ~~[00114]~~ The light 245 from the energy source (e.g. a laser or a broadband light source) is absorbed by a high absorbing substance [[350]] 250. The high absorbing substance [[350]] 250 transfers its energy to the conducting part 255 of intermediate material 230 [[340]] which is in contact with the target material 10 (e.g., skin ~~360~~). The rest of the cap area 270 [[370]] is made of an insulating material, which does not conduct thermal energy well. Thus, by controlling the size of the material of high thermal conductivity (HCS) [[340]] 255, one can determine how the size of the area to be affected. By controlling the power and the "on" time duration of the energy source, one determines how much energy will be delivered to a desired area size. By controlling the coolant duration and timing, one determines the duration of time for which the interaction is allowed to go on.

[00114] ~~[00115]~~ There are no scanners, no moving parts, no contact of the high absorbing substance with the skin, and no exposure of the skin to photons or any energy other then highly controlled thermal energy. There are also no microprocessors or programs needed to control the process. All operations are hardwired.

[00115] ~~[00116]~~ The highly absorbing substance 250 [[350]] in FIG. 2A, is consumed within a given amount of time and thus allows only a well-defined finite length of time for use.

[00116] ~~[00117]~~ The Size of the highly conducting material 255 [[355]] is adjustable to treat different areas, shapes, and sizes. Each highly conducting material 255 [[355]] is packed within its own cap [[370]] 230, and since the highly absorbing material is at least partly consumed by during operation, the caps are disposable caps.

[00117] ~~[00118]~~ The Energy source power and duration settings are presets and are designed to correspond to the size and shape of the highly conductive material.

[00118] FIG. 2B depicts a further embodiment of the invention, wherein one can raise the intermediate material 230 to allow directed application of the energy removing substance 210 (or coolant) to the target material 10. As shown in FIG. 2B, the intermediate material 230 is lifted up to allow the energy removal substance 210 to be applied directly to the target material 10 (e.g., skin) following the interaction.

[00119] FIG. 3A illustrates a replaceable cap 310 that can be attached to an exemplary device 315 having an energy source 325 and energy removal substance 330 for modification of target material ~~, 3030~~. The caps 310 ~~3035,~~ constitute the intermediate material 340 that absorbs the ~~source's~~ radiation 320 from the energy source 325 and conduct it to the targeted surface 335. Such caps 310 [[The cups]] may be arranged so that a certain portion of them is highly conductive and a certain portion of them is highly insulating. Further, part of the conductive portion of the cap 310 [[cup]] may be coated with material capable of absorbing well the energy from the source 325. For example in FIG. 3A, the energy 320 from the source 325 is scanned across the [[cup's]] cap's surface 340 [[3040]] that is facing the energy source [[300]] 325. The regions that contain the high energy absorbing substance 350 however, only absorb the energy. The regions that are made of high energy absorbing substance 350 can be made in different shapes as shown in FIG. 3B (see for example in patterns 370 ~~3070~~), or pattern 385 [[3080]] in FIG. 3C. Of course, a person skilled in the art will easily recognize that the patterns illustrated in FIG. 3B and 3C are merely very few representative examples and many other patterns of high absorbing material can be envisioned.

[00120] In FIG. 3A, a person skilled in the art will recognize that a beam 320 from the energy source 325 scanned across a portion of the cap 310 [[350]] and encountering the portion of the

cup with a high absorbing substance 350 will deposit its energy in said area according to the rate equation: Fluence=F_0*Alpha=P/(L Nu Dia)*Alpha, where F_0 is the energy delivering rate from a scanned source of power P, with a length of scan, L, and scanned frequency Nu, and beam diameter, Dia. The Absorption coefficient Alpha characterizes the high absorbing substance and determines what fraction of the delivered energy is actually absorbed and removed from the beam by the highly absorbing substance. Said energy will rapidly be conducted downwards to the outside surface 335 of the cap 310 [[335]] (i.e. the surface in contact with the target material).

[00121] The outside surface 335 of the cap 310 [[335]] is in contact with the target material and will be rapidly heated. Aluminum, for example, may conduct heat across 1 mm distance in 1 ms. Thus a cap with a thickness of for example 100 um may be conducted within 10 us.

[00122] Conduction in the lateral dimension is more difficult since it is more difficult to conduct heat in the lateral dimension through a very thin cup. Thermal conduction is accomplished most efficiently through energetic free electron motion and it is clearly more difficult to cram many electrons though a finite narrow passage.

[00123] In FIG. 3C [[3B]] we show an additional embodiment using an exemplary cup 310 [[3035]] with the intermediate material made mostly of a substance of high thermal conductivity (aka high conducting substance, HCS) 395, and with an inner surface made with an element that is ~~are~~ coated with a high absorbing substance 385. When the sources beam is scanned across the high absorbing substance 385 its energy is quickly conducted to the outside surface in contact with the target material. On its periphery, the high absorbing substance (HAS)-coated surface 385 may be encircled with a thin ring 390 of material of low thermal conductivity (i.e., insulator material). This insulator material ring 390 ensures confinement of the thermal effect ONLY to the desired area of HAS coating 385. Except for the ring 390 of thermal insulator, the entire cap 310 is made of a substance of high thermal conductivity. Thus, when the energy removal substance comes in contact with the inner surface, the entire surface [[is]] rapidly cools, thus ~~both~~ quenching both the hot thermal area and adjacent regions which may have been affected ~~effected~~ by thermal energy conduction through the target material itself. ~~This is illustrated in FIG. 3C where the intermediate material 3035 is made of a high conducting substance (HCS), 395. The high absorbing substance area 370, is thermally isolated from the rest of the HCS 395 by the ring of insulator material 390. when the energy source beam is scanned across the cap of~~

~~intermediate material, 3035, only the area 370 is heated. Heat is confined by the insulating ring to the HAS area 370. However, when the energy removal substance is activated, all the intermediate material area and the target material area in contact with it are cooled.~~

[00124] A complete device and its control box and knobs envisioned by a preferred embodiment of the present invention are illustrated in FIG. 4. A typical preferred embodiment for a device 400 [[4010]] consists of five components: a handpiece assembly 405, a connector cable 410, power cord 415, power supply console 420, and the footswitch 425.

[00125] Within the handpiece assembly 405 are several sub-components:

[00126] Diode laser [[4020]] 430: Emits laser radiation towards the scanning mirrors.

[00127] Thermoelectric cooler [[4030]] 435: Cools the diode laser 430 ~~, 4020~~ to prevent overheating.

[00128] Photodiode detector [[4040]] 440: The photodiode detector 440 is used to measure total output power. It compares the amount of photons detected from 4% of the reflected power from the beam splitter to the power output determined by the preset modes.

[00129] Scanning unit [[4050]] 445: The sub-components of the scanning unit 445 consist of mirrors, a lens, and a beam splitter. The mirrors are used to scan the laser emission across a section of the target. The window in the scanning unit is used as a beam splitter where it reflects 4% of the total output beam towards the photodiode detector [[4040]] 440. This allows for 96% transmission of total energy towards the target tissue. ~~A detailed picture of the scanning unit can be seen in FIG. 4.~~

[00130] Coolant ejector [[4060]] 450: The coolant ejector 450 sprays the contents in the coolant reservoir [[4070]] 455 onto the target tissue. The rate and duration at which the coolant is ejected is predetermined by the different preset modes. The ejector 450 sprays once every three scanned lines for a period time period determined by the mode that the device is operating in.

[00131] Coolant reservoir [[4070]] 455: The coolant reservoir 455 houses the coolant that is used by the coolant ejector~~, 4060~~ 450.

[00132] Focus guard [[4080]] 460: The focus guard 460 is mounted on the outside of the handpiece 405. Its length is used to determine to optimal distance from the end of the handpiece 405 to the target tissue. Resting the focus guard 460 on the target tissue does this.

[00133] Manual shutter, [[4090]] 465: The manual shutter 465 is used to prevent accidental firing of the laser. In its open position, it allows transmission of the laser beam to the target tissue. In its closed position, it allows no transmission of laser radiation outside of the handpiece 405.

[00134] The connector cable 410 [[4100]] is used to connect the handpiece 405 to the power supply console [[4110]] 420.

[00135] The power supply console [[4110]] 420 contains the control panel~~, 4120~~ 470 and houses the power supply [[4140]] 475. The power supply console 420 is plugged into wall via the power cord [[4150]] 415. The control panel [[4120]] 470 is used for turning the device 400 on or off, selecting one of the presets, and displays the system status. The control panel 470 is better illustrated and described in FIG. 5.

[00136] The footswitch [[4130]] 425 is used to operate the device 400. When depressed, power is supplied to the handpiece 405 that allows the laser diode and all systems within the handpiece assembly 405 to operate.

[00137] An exemplary device control box 420 with control panel 470 is shown in FIG. 5. The components of such an exemplary device control box 420 are as follows. The push button 510 represent an exemplary present button which, using an exemplary, preprogrammed microprocessor, allow the user to select a predetermined set of scanning, energy source power, and coolant parameters. Four exemplary preset buttons 510 are shown in this example. Above the ~~present~~ preset buttons 510 [[an]] exemplary light emitting diodes (LED) 500 [[is]] are shown. Such LEDs indicate which settings have been selected. An on/off button is shown by 520. The LED shown by 540 is a standby indicator that lights up when the device is idle. The LED shown by 550 indicates that the energy source is on and interaction with the intermediate and target material is occurring. The LED illustrated by 530 lights up whenever the energy removal components are activated.

[00138] As FIG. 6 shows, one preferred embodiment envisioned utilizing a diode laser 610 [[120]] as an exemplary energy source that is mounted on an thermoelectric cooler 615. A collimating lens 620 [[130]] ensures a collimated beam 625.~~, which then passes through the two scanner mirrors. From the scanner the beam is directed to a focusing lens 140 which directs the laser beam energy to the target tissue. Before emerging from the handpiece a small portion of the~~

~~beam is directed by the beam splitter 205 to a photodiode detector. The photodiode detector 200 ensures that the system is operated at a proper power level. The coolant reservoir 160 is also mounted within the handpiece. The coolant is ejected via the ejector 170, and directed towards the treated target tissue area. The focus guard 225, ensures proper positioning of the handpiece with respect to the target skin tissue. The manual shutter, 240, prevents accidental firing of the laser. Another possible embodiment makes use of a broadband light source as the source of energy (for example, a halogen lamp or a xenon lamp). Of course, in general, this invention contemplates many energy sources as a possible source. [00139]~~ The laser beam is emitted ~~from the diode laser~~ as a collimated beam 625, and is reflected from the first scanning mirror 630 ~~, 140,~~ onto the second scanning mirror~~, 150~~ 635. From there, the beam 625 passes through the focusing lens~~, 190~~ 640. Once the beam reaches the beam splitter [[205]] 650, a small portion, e.g., 4% of the laser output power ~~210,~~ is reflected by the beam splitter [[205]] 650, to the photodiode detector [[200]] 655, which is used to measure the total amount of power emitted by the diode laser. The photodiode detector [[200,]] 655 ensures that the system is operated at a proper power level. The remaining 96% of the laser output passes through the beam splitter 650 and focuses onto the target tissue 645.

[00139] ~~[00140]~~ The coolant reservoir [[160,]] 660 is also mounted within the handpiece. The coolant is elected via the ejector 665 and directed towards the treated target tissue area [[180]] 645. A manual shutter [[240]] 675 prevents accidental firing of the laser. The focus guard 670 [[225,]] acts as the positioning device that allows the user to properly determine the optimal distance to the target tissue 645 that will allow for optimal performance of the device.

[00140] ~~[00141]~~ If the manual shutter [[240]] 675 is not displaced, the shutter will block all transmission of the beam. Only when the shutter 675 is disengaged from its normal position will the beam be transmitted out of the handpiece and onto the target tissue 645.

[00141] ~~[00142]~~ FIGS. 7A through 7F illustrate several other preferred embodiment of the present invention including the patterns of good heat conductors on the intermediate material.

[00142] ~~[00143]~~ FIG. 7A shows a high thermal conductor `heaters` 720 which comprises part of the intermediate material (which we sometimes also designate at "caps") and the entire cap structure. The High thermal conductors heaters are separated by the insulator margin 750. Only the HTC 720, are heated due to the High absorbing substance HAS 730, deposited in one

end. Heat is conducted throughout the heaters 720 in the direction of the arrows 740. The HASs 730 is heated by the STATIONARY elongated BEAM 710. Thus, FIG. 7A illustrates the high thermally conducting `heaters` 720. The heaters, 720 are covered with the high absorbing substance (HAS) 730. The beam 710 is elongated and its long axis is aligned with that of the long axis of the heaters. The beam is then scanned across the intermediate material and gets absorbed every time it crosses each one of the HAS 730 covered heater 720. The rest of the intermediate material 760 is a conductor as well. Heat does not flow from the heaters to the rest of the intermediate material because it is insulated from the rest of the intermediate material conductor by the insulator brackets (750). Upon a predetermined timing an energy removal is activated and quenches the heating of the cell.

[00143] ~~[00144]~~ FIG. 7B shows the heating process completed by a scanning beam. Here, the entire length of a heater-strip of heaters 720 on the intermediate material 760, is coated by a high absorbing substance 730 and is heated by an elongated beam 710 which is then scanned across the surface and heat each one of the heater as it passes over it.

[00144] ~~[00145]~~ The entire process can also be made, in another preferred embodiment, by illuminating an entire pattern, as shown in FIG. 7C. The energy source in this case would be a large diameter, large area beam 710 which will irradiate and heat all heater at once. In this preferred embodiment, all the heater-strips 720 on the intermediate material 760, are coated by a high absorbing substance 730 and are heated by a broad beam, 710, which covers and heat all heater-strips at the same time for the duration of time for which the energy source is on.

[00145] ~~[00146]~~ Both of the above can be made, in another preferred embodiment, using an insulating intermediate substance as the intermediate material 760, said intermediate/insulating material, however, is thin enough to allow quick transfer of heat to the underlying target material. In this case, the High absorbing substance (HAS) is deposited on the insulator--intermediate material--in whatever pattern is desired. The energy source can then be scanned across the absorbers as in 7B, or can be large area as in FIG. 7C. The regions covered with HAS will heat up and transfer their energy to the target material and then, at a predetermined time, the device will activate an energy removing substance, for example a coolant spray, or a cryogen clay, to quench the heating and eliminate some of the pain and control the extent of the interaction and the tissue modification.

[00146] ~~[00147]~~ FIG. 7D illustrates an exemplary cap 776 comprising of an intermediate material 777 on which a High absorbing substance can be deposited, and a holder 779 that can be attached, via the guiding tube 783, to the handpiece containing the energy source and the energy removing substance.

[00147] ~~[00148]~~ FIG. 7E shows that cap 776 attached with an intermediate material 777 on which a High absorbing substance can be deposited, with its holder 779, attached, via the guiding tube 783, to the handpiece 781 containing the energy source and the energy removing substance.

[00148] ~~[00149]~~ In a further preferred embodiment the effect of the energy removal substance interacting directly with the target material or interacting with the intermediate substance absorbing the source's energy can be further controlled through the action of an auxiliary source of energy (or the same energy source activated again for additional periods and acting in coordination with the energy removal substance) in order to mitigate excessive energy removal effect or excessive cooling (which may cause harm to the target material.) For example, in FIG. 7F if the time axis is represented by the line [[7035]] <u>785</u>. Then a burst of energy <u>787</u> [[7005]] at time <u>788</u> [[7006]] may be followed by the application of the energy removal substance <u>789</u> [[7015]] at time [[7016]] <u>790</u>. Then, in order to control or mitigate the effect of the energy removal substance, the burst <u>789</u> [[7015]] is followed by a second application of a burst of energy pulse <u>791</u> [[7025]] at time [[7026]] <u>792</u>. If the target material removal or modification process occur repetitively, then the energy/energy-removal/energy application cycle is repetitive as well as shown by the additional sequences <u>793</u> [[7040]] and <u>794</u> [[7050]] in FIG. 7F.

[00149] ~~[00150]~~ FIG. 8 shows another preferred embodiment of the present invention. In this embodiment, a grid 810 made of a rigid material is attached to a film of a substance of high absorption 820 to form an interface between the impinging source's energy and the target material. The film of substance of high absorption 820 is in contact with the target material, while the grid 810 is facing the energy source. The grid 810 can be made of aluminum or any other substance. It may be made of material that does not absorb the source energy very well. The energy from the source, passes through the openings in the grid and is then absorbed by the film of high absorbing substance 820 and is then transferred to the target tissue. The energy is either not absorbed well by the grid or if absorbed, is not sufficiently damage the grid. The grid

810 may also serves as a active cooling to cool the target material and the high absorbing substance film. The grid 810 may, for example, function as a thermoelectric cooler where each line on the grid is triggered at a different time (for example, cooling can be triggered so that cooling a line on the grid is triggered to follow an energy scan along or in the vicinity of that line. This phased cooling can assure efficient interaction at, for example, the region parallel to grid line 840 while the region parallel to the area 850 [[840]] is being infused with energy from the energy source. One exemplary way to prepare such a grid 810 is to use a metallic thin sheet cut out to the desired dimensions, create a perforation pattern in said thin sheet of metal and then, attach the film of high absorbing substance to the sheet of metal.

[00150] ~~[00151]~~ In another preferred embodiment, shown in FIG. 9, an apparatus is contemplated by the invention to allow different focusing lenses to create different spot sizes at the high absorbing substance. In this embodiment, a telescopic attachment 910 to which a high absorbing substance intermediate material cap 920, is capable of being extended or folded to the desired length from a position, 930 to which a corresponding lens can be attached. The Operator can thus insert a variety of lenses with different focal lengths (thereby creating a range of target effects) and adjust the telescopic attachment 910 to the corresponding proper length. The lenses 950 can either be inserted one by one to a lens holder position 930, or they can be all mounting on an exemplary revolving carrousel or drum 960, said revolving carrousel or drum 960 is placed at the lens holding position 930. The operator can then rotate the revolving carousel or drum to the position where the desire lens is engaged and adjust the telescopic attachment 910 to the proper position. Of course the entire process can be automated and driven by a motor so that the operator can select the target or tissue effect he wish, the drum is automatically rotated to the proper position with the proper lens selection, and the telescopic attachment 910 is automatically adjusted by motor to the appropriate extended length. Also shown in FIG. 9 is an optional energy removal system 970. Such energy removal system can consist, for example, of a coolant reservoir and ejection control, 970, which, for example, on demand, allow an exemplary jet of coolant spray 980 to discharge and be directed toward the intermediate material medium 920 with the high absorbing substance. The cooling of the intermediate material medium also remove energy from the target material and thus the cooling of the both the intermediate material as well as the cooling of the target material is achieved.

[00151] ~~[00152]~~ Controlling Tissue Effects:

[00152] ~~[00153]~~ The present invention contemplates four interacting parameter regimes that yield to the final target modification effect. The conversion efficiency (i.e. how much of the incident energy has been converted to thermal energy) depends strongly on the interaction between these four factors, depicted schematically in FIG. 10: The energy source parameters (Lp or P_L) 1010, the energy manipulating components parameters (OS p or $P_{o/s}$) 1020, the high absorbing substance parameters (HASp or P_{has}) 1030, and the Energy removing parameters (ER p or P_{er}) 1040~~, and the high absorbing substance parameters (HAS$_p$). The present invention contemplates four interacting parameter regimes that yield to the final target modification effect. The first parameter group to be considered is the source parameter. These include the source energy, the source power, the pulse duration (if pulsed) and Pulse repetition rate (if pulsed), and the source wavelength, if the energy is radiated~~.

[00153] The first parameter group to be considered is the source parameter P_L 1010. These include the source energy, the source power, the pulse duration (if pulsed) and Pulse repetition rate (if pulsed), and the source wavelength, if the energy is radiated.

[00154] The second group of parameters is the optical/scanning parameters, $P_{o/s}$ 1020. These define the beam spot size and the motion of the energy along the intermediate material

[00155] The third group is intermediate material parameters, including high absorbing substance parameters P_{has} 1030. These define the rate of conversion of energy from the source energy to the type of energy that interacts with the target.

[00156] The final group of parameters is the energy removal parameters P_{er} 1040. These define when, how and temporal nature of the energy removal from the intermediate material/high absorbing substance, target material or both.

[00157] The interaction between these four components will determine how much of the source's energy is converted to thermal energy. For example, a 1 W source scanning a 1 Cm^2 area of at a rate of about 6 seconds has been tested. Assuming that all the energy is absorbed by the layer of high absorbing substance, we have 6 Joule deposited over the 1 Cm^2 area.

[00158] Assume now that the energy absorbed E is thermally conducted to the underlying target area. In the case of human skin, for example, water molecules dominate the underlying

tissue cells. Simplifying our analysis by assuming as a first approximation a tissue model which is similar to an equivalent volume of water, we can estimate the amount of energy it would require to take a coagulate (i.e. bring the tissue temperature to above the temperature of thermal denaturation of approximately 60° C.) a volume of tissue (100 μm*1 cm^2) approximated as a volume of water.

[00159] We can use the relationship $E=C\Delta T$ (1) Where E is the energy required and AT is the increase in temperature. To take water from 20 degree c to 60 degree c and with the specific heat of water given by approximately Cs=1 cal/g*c° We get from the relation above $E\approx 1.6J$

[00160] To vaporize this amount of tissue would require bringing the tissue (or in our simplified thermal model--the water volume, 1 cm^2 100 μm thick) to boiling temperature, and then, further vaporizing that volume. From the relationship of Equation 1 above, the temperature rise of 80° C., would require about 3.2 J. The heat of vaporization of water at 100° C. and 1 atmosphere pressure is 539.6 Cal/gm. Thus to vaporize the 100 um thick volume discussed above will require bout 21.6J, clearly much more than the TOTAL incident source energy in our experiment of about 6J. On the other hand, a 10 mm thick layer of tissue (approximated as water) will require only approximately 0.32 J to raise its temperature from 20° C. to 100° C., and 2.16 J to vaporize. With our above calculations show that to raise an addition volume of (100 μm·1 cm^2) to 60° C. coagulation temperature is about 1.6 J, we see that with a total of about (2.16 J+0.32 J+1.68 J=4.16 J we can vaporize about 10 μm of tissue and coagulate an additional 100 μm thick layer.

[00161] This simplified analysis agrees with the order of magnitude of our experiments in pig skin tissue, in which both the depth of ablation and depth of tissue thermal damage are on the order of magnitude predicted by the above analysis.

[00162] 1) From the above analysis we can conclude that coupling of X Joule of energy with temporal T(t) and spatially R(r) of energy will lead to the ablation of a layer of thinness Xabl and leave behind a layer of thickness Xtd of thermally modified tissue. The present invention contemplate four parameter groups responsible for a given energy distribution $E(t,r)=F[T(t)R(r)]$.

[00163] The example above showed that a given parameter combination with 1 W of 810 nm radiation, allows, for example, the generation of 10 um deep ablation zone and a subsequent thermal modification zone of approximately 100 um deep. Such an exemplary combination

generated 6 J of energy, of which, according to the above analysis, about 4.2 J was needed to generated these effect. If we define this energy as Eth, or threshold energy for interaction, which when applied in conjunction with the parameter combination ~~540 of FIG. 5~~ 1050 of FIG. 10, will result in the Zabl=10 um and Ztd=100 um.

[00164] Clearly, when considering the parameter involved in the substance of high absorption (HAS)~~, 530~~ P_{has} 1030, if a single layer of absorbing particles is involved, the surface density of absorber will correspond to the amount of energy coupled to the substance of high absorption and the total amount of incident energy converted into thermal energy. For the parameters in the incident power 1W, 810 nm, with scan rate of 1 cm^2 per six seconds, described above, a single layer HAS with particle density such that only, for example, 1/3 of the target area is cover, will not provide sufficient energy to achieve the effect of vaporizing 10 um of tissue and thermally modifying 100 um. While thermal diffusion will provide thermal effect even through the gaps in the surface coverage, (for example, if a heat-removing substance is applied every 250 ms, heat diffusion of about 500 um within this time, would essentially assure complete coverage of the target surface by energy) the total amount of energy deposited in the tissue will be 2/3 less then in a uniformly covered surface as the portion of the beam that does not encounter HAS particles, continues to propagate through the skin unimpeded.

[00165] 2) On the other hand, if E>Eth, then one can compensate for the high absorbing substance, HAS, lower particle density, with a higher source power. For example, if in the experiment discussed above we employ a power source of, for example, 3 W, the sources now deliver 18J in 6 sec, and while 1/3 of the particles will couple approximately 1/3 of the energy, the same total quantity of energy will be coupled to the targeted. Heat diffusion will then assure that this same overall quantity of coupled energy will be distributed to the entire area.

[00166] With a spot size of, for example, about 200 um and a dwell time of about 10 ms, even small, roughly single micron size particles, will allow heat diffusion to roughly the same area on the same time scale. Thus a uniform HAS particle coat with a 1W beam dwell time of about 10 ms will cover about he area with thermal energy as a coat with 1/3 the particle density but with a 3 W power.

[00167] The above discussion thus demonstrate that the parameters combination ~~540 of FIG. 6,~~ 1040 of FIG. 10 allow compensation of sources power by varying the High absorbing substance concentration and vice versa.

[00168] 3) The thickness of the high absorbing substance is another component[[s]] of the parameter group ~~530 of FIG. 6~~ 1040 of FIG. 10 that plays an important part in determining the target (or tissue) effects. If the absorbing particles are poor thermal conductors, depositing a multiplayer absorbers on top of the target will result in significant source's energy being absorbed in the upper layers but never making it to the lower layers before the heat remover is applied. ON the other hand, applying [[a]] high absorbing particles in suspension in a substance with improved thermal conductivity will assure that the above energy is conducted to the target material. One can then allow gradual thermal energy application to the target as sequential scan passes are stacked and add their thermal energy to the tissue. The present invention contemplates ablatively removing portion of the high absorbing substance coat with each pass resulting in a self-limiting scheme allowing only a finite number of passes and thus only a finite amount of energy deposited in the target material before the high absorbing coat has been completely removed and no more sources energy can be coupled to the target.

[00169] 4) Controlling Tissue Effects Through the Heat-Removal Mechanism. The energy removal mechanism ~~520~~ 1040, illustrated in ~~FIG. 5~~ FIG. 10 also plays a multiple role in controlling the tissue effect. As was pointed in the discussion above, it effectively ends a heating cycle by effectively removing the heat from the outer surface of a target. For example, if a single line 1 cm long and 0.7 mm wide is scanned in, for example, 100 ms, then heat diffuses about 300 um from the impacted zone. Activation of the heat-removing mechanism ~~(according to the pattern shown, for example, in FIG. 3)~~ allows control of spatial distribution and synchronized termination of the thermal effect (by effectively removing the heat source from the surface). In fact, the action of the heat removal mechanism goes even further, because by allowing the operator to very rapidly readjust the surface temperature to even below normal ambient temperature, heat can now be forced to flow out of deeper layers in the tissue. The net effect is creating a spatially and temporally controlled thermal pulse that propagates into the material bulk from the high absorbing substance in contact with the material surface layer and then, upon instruction from the operator, the heat reverses direction and flows out of the bulk.

[00170] An analogy to the behavior of the flow of thermal energy in the material and the time and space dependence of the distribution of thermal energy density (thermal energy per unit volume) is the behavior of an electric charge density (for example electrons density) under the influence of alternating positive and negative electrodes outside a conducting medium. The thermal energy density under the influence of the deposited light energy (effect of ~~530 in FIG. 5~~ 1010 in FIG. 10) and the heat removing mechanism, ~~520~~ 1040, (such as freon like spray or other cryogen spray or controlled air flow, or temporary contact with cold plates or thermoelectric coolers or other such methods to induce transient heat removal), is much like an oscillating or direction-reversing electron cloud movement.

[00171] The following are additional preferred embodiments (PE) contemplated by the present invention. The discussion below will also demonstrate the relationship between the various parameter groups of ~~FIG. 5~~ FIG. 10.

[00172] Preferred Embodiment 1: Optical heating. Here, no high absorbing substance and no heat removal mechanism are used, such that the heat transfer substantially amounts to diffusion In this case. Initial thermal energy distribution mirrors that of the optical deposition. Heating due to optical scattering is maximal just below the surface.

[00173] Preferred Embodiment 2: Heating with a heat removal applied before and or during irradiation, resulting in peak power and thermal energy distribution below the surface.

[00174] Preferred Embodiment 3: Heating the target surface optically resulting in initial thermal distribution which mirror the initial optical distribution, Heat removal is then applied to the surface resulting in modification of thermal distribution below the surface as well as heat begins to redistribute itself and diffuse BACK UPWARD towards the now cooler surface. Thermal modification thus does not allow enough time for surface to get fully heated and damaged. Thermal distribution below the surface is temporally and spatially modified according to intended operator design.

[00175] Preferred Embodiment 4: Application of a highly absorbing substances to the target surface prior to external energy deposition. This leads to initial heating confined to the THICKNESS OF SURFACE high absorbing substance alone. The operator thus has full control over the deposition layer and the initial heating zone.

[00176] Preferred Embodiment 5: Initial heating with high absorbing substance allowing heat to propagate ahead a predetermined distance. A heat removal mechanism is then applied to the surface quenching the surface heating. The heat then continues to diffuse deeper into the tissue but the thermal energy below the surface also flows back out and flows back towards surface where it is used to reheat surface. The net effect of this process is to limit the effect of the heating, the amount of heat available for tissue modification and the extent of the damaged tissue and the depth location of damaged tissue.

[00177] Preferred Embodiment 6: The high absorbing substance is applied and subsequently wiped off so it remains substantially mostly in the pores, depressions and troughs of the skin. In these location it absorbs radiation causing localized points of thermal heating spatially distributed on the target surface. Subsequent illumination but the external energy source, results in some of the radiation being absorbed by the localized points containing high absorption substance while the rest of the radiation propagates deeper and heating--to a much lower degree--much deeper into the tissue. The net effect is rapid heating and expansion of the pores COMBINED with heating of lower/deeper region of the skin to allow expansion of the lower parts which, in turn, expel through the pores, undesired material which may reside in the skin.

[00178] Preferred Embodiment 7: The preferred embodiment above (PE6) followed by the removal of heat. "Freezes" and the expansion on the surface (and begins generation of contraction of the target material) while heating of deeper regions by Optical deposition allows an efficient deeper target expansion.

[00179] Preferred Embodiment 8: The process then of application a high absorbing substance can be modified through a high absorbing substance applicator device to achieve the following effects:

[00180] a) Heating of a very thin layer of high absorbing substance. Heat is transferred to the skin.

[00181] b) Heating of a "diluted" high absorbing substance suspended in a layer of other material

[00182] c) Wherein other material is an insulator--thereby mitigating the amount of heat transferred but also maintaining heat in that layer for a longer time.

[00183] d) Wherein the other material is an insulator--thereby mitigating the amount of heat transferred down to the lower tissue but allowing accumulation of heat in the surface layer lowing to material removal through explosive ablation of the applied surface layer.

[00184] e) Wherein other material is a conductor--thereby enhancing heat transfer to the tissue.

[00185] f) Whereby the above method is followed by surface heat removal.

[00186] g) Where the high absorbing substance is also insulating thus resulting in ablation of surface with substantially mostly mechanical shock to tissue.

[00187] h) Wherein the high absorbing substance is partially transmitting resulting in BOTH deeper "Optical" heating AND intense surface heating.

[00188] i) The device and method of 8 above wherein the heating phase is followed by heat removal resulting in intense heating at below surface but a more delicate spatially larger heating at the surface.

[00189] <u>Preferred Embodiment 9:</u> Application Technologies. Application of high absorbing Substance Using a Thin Film: Another way to create a precise effect with the disposable is to create a film. For example one can create a uniform suspension of high absorbing substance in a host material such as paraffin, paper, metallic matrix, insulator matrix, thermal insulator or plastic matrix, thermally conducting matrix, Jelly, agar or other hosting material. The operator can then slice it to a precise thickness (for example from a preferred thickness of about 10 micrometer to as much as about a 100 micrometer thick--although many other thickness can be contemplated). The process is much like that used in histological slides preparation. A slice with the desired particle size and the desired concentration is prepared and is coated with adhesive to allow it be attached to the targeted area of the skin

[00190] Such a film of HAS can be packaged in a sterile packaging and can come in various sizes and shapes. Such a package can then be opened prior to use, and the operator can cut it with sterile scissors to the desired shape. The film is then attached over the desired targeted area creating a precise special localization of concentration and density and particle size and thickness of layers.

[00191] Light traveling through the film containing the high absorbing substance, activates the product in order to cause thermal injury to tissue and/or the high absorbing substance itself for the purpose of causing thermal injury to tissue. The solid film become adhesive upon contact with moist target and adheres to a given location. The adhered film allows high spatial control and eliminates the more messy cream or lotion method of applying a substance of high absorption. The film visually changes in color as the high absorbing substance interacts with the incident energy. Some portions of the film are consumed by the applied light source. The consumption of the film shows the operators where they have treated, and how long and when the product has expired.

[00192] With the film or cream of high absorbing substance in place, an site undergoing interaction is visually altered and the handpiece may be used in a free hand motion to cover a larger area. The film will change in appearance, showing the area treated and Confirming the product has been consumed. The operator continues to move the handpiece over the target area until the film changed its appearance uniformly to the one indicating proper treatment. The film may be designed to be thin enough so it does diminish the effectiveness of thermal energy conduction due to the energy source or heat removing source that are heating or cooling the skin. The film may incorporate anesthetics drugs nutrients and coolants that could allow the film to have it own cooling mechanism built into it.

[00193] <u>Preferred Embodiment 10</u>:

[00194] The Device contemplated includes an energy source which emit radiation which, in turn, is absorbed by the an intermediate material made of thin layer. One surface of the intermediate layer contains an absorbing substance, which is capable of absorbing the radiation of the energy source inside the handpiece. A second property of the intermediate substance is that it is capable of transmitting said absorbed energy from the side facing the energy source to the side in contact with the target material (the material to be modified). A third property of the intermediate material is that all the absorbing substance is contain in a region of the intermediate material, which is accessible to the radiation from the energy source but which is--in a preferred embodiment--NOT in contact direct contact with the target material.

[00195] In an alternative embodiment, the intermediate material contains absorber that IS in contact with the target material. However, said intermediate material and the high absorbing

substance of this embodiment are made of biocompatible material which can be used in contact with an animal skin without causing adverse effect. In the more general case, said high absorbing substance and intermediate material can be in contact with the target material but are made of material which DOES NOT have adverse effect on the target material. For example, High absorbing material can consist of carbon particle in solution as in Higgins Black Magic ink. A paper matrix can be a 0.05 mm thin paper with the carbon solution capable of adhering to the surface of the paper film.

[00196] Further preferred embodiments for the application of high absorbing substance:

[00197] A) The composition of the high absorption substance can be adjusted for an optimal tissue modification. The matching to optimize the interaction ~~540 in FIG. 5~~ 1050 in FIG. 10 is accomplished by adjusting the source parameters P_L 1010 ~~500~~ and Optical/scanner parameters Po/s ~~510 in FIG. 5~~ 1020 in FIG. 10, to that of the high absorption substance parameters P_{HAS}, ~~530~~ 1030.

[00198] Settings for Laser/Optical/Scanner:

[00199] The fluence F at a given point and time on the target surface is given by, $F=P/(L_x NU_x D)$ where P is the source's power in Watts, Lx is the length of scan in the X-direction (the horizontal direction), NU_x is the scan frequency in the X-direction and D is the spot size diameter. The actual energy in the tissue is determined by a combination of the effect of the energy absorbed by the high absorbing substance and its conduction coefficient (CC) responsible for transferring the thermal energy to the tissue. Thus, the thermal energy transferred to the tissue (recall that the fluence is simply the energy per unit area) is proportional to E tissue≈(E absorb in cream)*Conduction coefficient. Now if we use an absorber which also acts as an insulator in the medium, the conduction coefficient then becomes a function of the high absorption substance density (ρ). E abs=FUN(ρ). If we design the high absorbing substance (HAS) as a good insulator, material conduction will in general decrease as a function of HAS density ρ. With these considerations we have effectively designed a system such that incident energy conversion to thermal energy is increase with the HAS density BUT the transfer of this thermal energy from the layer of HAS to the targeted material surface is DIMINISHED with increase HAS density. This situation is depicted by ~~FIG. 7~~ FIG. 11 below .

[00200] As shown in ~~FIG. 7~~ FIG. 11, the absorbed energy ~~710~~ 1100 increases with HAS density ~~700~~ 1110, while the transferred thermal energy to the tissue ~~720~~ 1120 is decreased as a function of HAS particle density 1100. The total amount of energy transferred to the targeted material surface 1130~~, 730,~~ is thus, a combination of these two effect and is demonstrated in ~~FIG. 7~~ FIG. 11 by the curve ~~740~~ 1140. Optimal and maximum thermal energy deposition in the targeted tissue surface is corresponds to the location 750 shown in ~~FIG. 7~~ FIG. 11. The curve ~~720~~ of transferred thermal energy 1120 shows the tendency to decrease coupling due to increase in HAS particle density and the associated decrease in thermal conduction. The curve of absorbed energy ~~710~~ 1100 shows the tendency to increase energy coupling with increase in HAS particle density and increased absorption. The curve ~~740~~ 1140 shows the actual effective energy coupling to the target material surface due to the combined effect of curves of absorbed energy 1100 and transferred thermal energy 1120. ~~710 and 720~~

[00201] The correct calculation of the amount of energy deposited in the target material should thus be $F_{effective}=P_{effective}/(L\ NU_xDiamter)$ where $F_{effective}$ is given by $P_{effective}$=(Incident power*Absorption).

[00202] To calculate a manipulation of the beam power as a function of HAS particle density we follow the procedure below: We Assume a uniform complete absorption in tissue when $\rho=P_{ideal.}$ We then assume that when $F=F_{ideal}$ one gets the desired tissue effect. We Set laser/optic/scan parameters--Power, Lx, NUx and beam diameter at the target so that to $F>>F_{ideal.}$ So we are certain that a thermal damage to the target material will occur. We then REDUCE ρ to $\rho<\rho_{ideal}$ so that LESS power is absorbed and the incident fluence is again in the close of the "ideal" fluence F_{ideal}.

[00203] Obviously the dependence of HAS particle density on Laser/optical/scanner parameters to achieve a desired tissue or target effect allow a large number of permutation and large number of combinations to be selected. If a Different high absorbing substance (HAS) particle density ρ is provided and if the HAS particle density is too low--no effective interaction occurs On the other hand, if the HAS particle density is too high--a burn might occur. If HAS particle and the host substance are maintained at a constant conductance level, the deposited energy density will increase monotonically as a function of the HAS particle density until the

energy removal substance may be applied directly to the surface of the material to be modified, thus allowing a very efficient energy removal.

[00351] In such a device, the intermediate material substance could comprise ~~(See FIG. 101A)~~ partially reflecting substance so that partial perforation of the HAS film or HAS cap or HAS cartridge results in detectable drop [[~~In~~]] <u>in</u> the backscattered radiation level. This backscattered light is detected by a detector substantially feedback the signal to the source, automatically stopping the source from emitting energy if said signal level drops below a predetermined level. could be highly absorbing and not thermally conducting but a few reflecting substance element are dispersed on the surface of the intermediate material substance facing the energy source. The reflected energy is then detected by a photo-detector. If said reflected energy drops below a certain level, thus indicating possible perforation of the HAS cap, the energy source is immediately disabled. This will ensure that no energy comes out of the cap if said HAS cap is perforated or otherwise allows energy leakage.

[00352] Viewed from another perspective, a method and a device for controlling the distribution of energy in a target material, wherein the surface is heated by energy of the source absorbed by the high absorbing substance , and is then diffused to the surface of the material to be modified. This source energy absorption at the surface by the high absorbing substance (HAS) is then converted to thermal energy and diffuses as thermal energy into the material to be modified material in the direction of the arrows. On the other hand, some of the source energy is allowed to pass through the intermediate material substance.

[00353] This direct source energy passing thorough the windows, is then scattered as it propagate through the material to be modified, essentially creating source energy diffusion (or optical energy diffusion if the source energy is optical in an exemplary case). The diffused source energy penetrates much deeper into the target material, and then gradually is absorbed by the target material thus creating much deeper thermal (or even mechanical or chemical effects). The combination of low lying diffusion thermal energy and deep-penetrating source energy allow the operator to tailor and engineer any spatial energy distribution desired.

[00354] Finally, methods and devices are contemplated for creating thermal (as well as source energy/thermal energy effect at the targeted material, while allowing rapid energy removal at the end of the energy deposition cycle. A highly conducting intermediate material which is also